

## REMARKS

Careful consideration has been given to the Official Action of September 26, 2003 and reconsideration of the application as amended is respectfully requested.

Claims 1-30 have been examined by the Examiner.

Claims 1-5, 8, 9, 19, 22-24, 29 and 30 have been rejected under 35 U.S.C. § 102(b) on Medoff.

Claims 6, 7, 10, 11, 15-17, 20, 21 and 28 have been rejected under 35 U.S.C. § 103 as being unpatentable over Medoff in view of Orbay.

In order to clearly distinguish the invention from the cited art, amendatory action has been taken in the claims. Allowable claims 12, 18 and 25 have been written in independent form and are considered to be in allowable condition along with the claims dependent therefrom.

Claims 31-37 have been added.

A fundamental distinction between the present invention and the cited art is that after an interfragmentary pin has been installed to secure the fracture, the

end of the pin is bent and thereafter a fixation plate is mounted on the bone structure such that a groove in the fixation plate receives the bent end to restrain the pin to prevent backing out of the pin and movement of the pin in the lane of the plate.

Medoff secures the pin after it is installed in a hole in the plate, for example, by bending the pin. Orbay installs a fixed angle rigid post, such as a screw through a hole in the pin.

The claims which have been rejected on Medoff under 35 U.S.C. § 102 have been amended to recite specific structure of the groove in the plate and its cooperation with the bent end of the pin. Medoff lacks this construction and is not applicable as an anticipatory reference.

The Examiner contends that Medoff discloses a plate that secures one end of a pin from translational displacement, and that it would be obvious to provide grooves on the undersurface of the plate based on Orbay. The other cited references show devices in which a fixed angle solid post or tine is physically connected to a plate, to prevent the post from backing out. The Examiner's rejection fails to address the inventive features associated with the fixation of the pin according to the invention.

First, it is pointed out that the use of a pin plate or fixation plate is

directed at supplementation of the fixation of an interfragmentary K-wire (pin). Because the fracture lines are variable, the surgeon does not know what is the optimal angle to insert the K-wire. Because of this, the wire may be directed within a range of angles and there is no way to predict the specific angle required until the fracture site has been opened and the fragments restored to their correct positions. Hence, the pins are installed at any selected angle by themselves without the plate.

Since the plate must accommodate a complete range of relative insertion angles, the references cited with fixed angle holes would not be effective. Plates with fixed angle holes can only connect the post to the plate as long as the post is directed along a single, predetermined axis of the hole. The ability to restrict a pin that may be inserted within a range of angles from backing out of the plate is not suggested by any of the fixed angle plate designs.

It would not be obvious to combine the grooves in Orbay with Medoff to arrive at the claimed invention. Orbay uses a wire as an "extending tab" to the plate, in order to provide a little extra length of the plate to buttress the superficial surface of the bone adjacent to it. The wire serves no function of restraining the post which itself is secured to the plate. This extending wire is shown as a U-shaped uniplanar wire, or as a single wire with a small hook at the end. The functional requirement for Orbay's grooves is to act as a cantilever to securely hold a linear wire at one end to prevent the fragment from displacing in

a more superficial direction. This is a completely different concept than providing a means to prevent an interfragmentary wire from backing out axially. In Orbay's patent, the wire is subject to considerable bending forces (and therefore not a very effective design). In a different embodiment, a hook is added to the end of the wire but only serves to try to restrict slippage of the bone fragment from under the wire. In sharp contrast, the interfragmentary pin in the Application is a sufficient fixation element in its own right, much like a nail that connects two pieces of wood. The concern with the interfragmentary pin is that it does not back out, thereby losing its penetration of the deep fragment. The locking pin plate addresses this problem and as such, it represents a feature not obvious by simply combining Orbay with the plate of Medoff. In fact, Orbay's U-wire is not an interfragmentary pin and its ends are fixed in the channels of the plate. There is not the remotest suggestion of providing a groove in the pin plate which "captures" the already bent end of the K-wire as in the present invention.

The locking pin plate of the invention also addresses the issue of preventing axial backout of the K-wire, in addition to translational displacements of the K-wire for the situation in which the K-wire is inserted before the plate is placed on the wire. This means that the K-wire must have properties which make it stiff enough to provide adequate interfragmentary fixation between two independent bone fragments, yet at the same time be flexible and malleable enough to allow the protruding end of the wire to be bent and received by the plate that provides fixation. This combination of flexibility and stiffness in proper

proportions is also not a feature that is addressed in any of the previous cited references (with the exception of Medoff) and forecloses any combination of the rigid posts of Orbay with the interfragmentary K-wire.

Claim 1 has been amended to incorporate subject matter from claims 2 and 3 to define with particularity the groove in the plate and the configuration to engage the bent end of the pin to restrain the pin.

Claim 5 has been written in independent form and is directed to the embodiment of Fig. 6 where the bent end of the pin is restrained under the fixation plate. This is completely absent in Medoff, Orbay and the other cited art.

Claim 15 has been rewritten in independent form and recites the bent end of the pin and the groove in the plate to receive the pin.

Method claim 29 has been amended to reorganize the steps to clearly set forth that first the end of the pin is bent and then the plate is mounted on the bone structure to engage the bent end in the groove in the plate. Medoff bends the end of the pin after it is placed in the plate hole. In Orbay, the interfragmentary member is a rigid post which is not bent.

Method claim 30 is unamended and recites a welding step to secure the pin in a hole in the plate after the pin is inserted in the hole. There is no such

method of securing the pin in the plate in the cited art.

Claim 31 is a method claim dependent from claim 29 and recites additional steps of insertion of the bent end into the groove which partially extends in the thickness of the plate.

Claim 32 has been added and is dependent on claim 1 and further defines the structure by which the bent end of the pin is accommodated in the groove upon placement of the plate on the bone structure.

Claim 34 has been added and is directed to the embodiment of Fig. 6A in which a dimple is provided in the lower surface of the fixation plate to receive the projecting end of the pin to restrain it from backing out and shifting in the plane of the plate. Medoff discloses complex means of restraining the end of the pin after it extends through a hole in the plate and above the plate (see col. 5 beginning at line 34; at line 46; and at line 50).

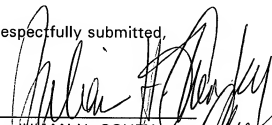
Claims 35-37 are directed to the fixation plate with the groove therein for restraining the bent end of the pin. Medoff shows a through slit in the plate which serves a different purpose namely to permit snap engagement of the pin in the hole in the pin plate. Orbay discloses through channels in which wires for extending the plate are fixed.



In sum, neither Medoff nor Orbay provide any suggestion as to the restraint of the interfragmentary pin by the plate according to the invention as Medoff relies on bending the end of the pin after the pin has passed through the pin hole in the plate whereas Orbay uses rigid posts which are threaded into the holes in the plate and require no fixation means as in the case of bendable pins which are first pinned across the fracture and subsequently secured by the fixation plate without any need for subsequent fixation of the bent end of the pin.

For the above reasons, it is respectfully submitted that all of the claims now present in the application are in allowable condition and early and favorable reconsideration is requested.

Respectfully submitted,

  
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